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09/302,239	04/29/1999	GARY L. NELSESTUEN	09531/005001	6644

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EXAMINER	
SCHNIZER, HOLLY G	
ART UNIT	PAPER NUMBER
1653	21

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Please find below and/or attached an Office communication concerning this application or proceeding.

FILE COPY

Office Action Summary	Application No. 09/302,239	Applicant(s) NELSESTUEN, GARY L.	
	Examiner Holly Schnizer	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-14,16 and 17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1, 3-14, and 16-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims/Final Rejection Withdrawn

The Amendment and Response after Final Rejection filed 8-12-02 has been entered and considered. Upon review of the parent application (appl. No. 08/955,636, now U.S. Patent No. 6,017,882) new issues of double patenting have been raised. Therefore, the Final Rejection of 6-18-02 has been withdrawn.

Claims 15 and 18-22 have been cancelled. Therefore, Claims 1, 3-14, and 16-17 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-14, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims still recite substitutions at particular amino acid residues without placing the amino acid residue in the context of a sequence. For example, claim 1 refers to "residue 11" in line 4. Is residue 11 intended to be from a Factor VII sequence? The examiner suggests correcting the claims such as the following example for Claim 1:

"...comprising at least one amino acid substitution at [residue 11 (corresponding to] residue 10 of SEQ ID NO:3 or SEQ ID NO:4[) or 29 (corresponding to] at residue 28 of SEQ ID NO:3 or SEQ ID NO: 4[)]." (Without the marks, this section of the claim would read, "...comprising at least one amino acid substitution at residue 10 of SEQ ID NO:3 or SEQ ID NO:4 or at residue 28 of SEQ ID NO:3 or SEQ ID NO:4.").

The claims are drawn to factor VII or VIIa sequences and the sequences of SEQ ID NOs: 3 and 4 (factor VII sequences). It appears that residue 11 of Claim 1 may refer to the factor IX sequence. Since the claims are drawn to factor VII sequences, the claims would be clearer if only factor VII amino acid positions were used in the claims. The specification, at page 9, lines 14-19, indicates that the amino acid positions given throughout the specification are numbered according to factor IX and that factor VII has one less amino acid and must be adjusted accordingly. Therefore, an amendment such as suggested above would not introduce new matter. Clarification of the claims is required.

Claim 1 is confusing as to how many substitutions may be made. The claim states "at least one amino acid substitution" implying that more than one substitution in a single protein may be made. However, the claim states that the "at least one amino acid substitution" is at position 11 or 29 implying that either one or the other position may have a substitution. Such inconsistency causes confusion in the dependent claims as well. Clarification is required. If more than one substitution in a single polypeptide is intended then changing "or" to "and/or" is suggested.

Double Patenting

Duplicate Claims

Claim 11 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 6. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

In the present case, it appears that both claims are directed to a polypeptide of claim 3 with an additional substitution of a phenylalanine or glutamate at position 29.

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-14, and 16-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 6,017,882.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claim 1 of U.S. Patent No. 6,017,882 recites a vitamin K-dependent polypeptide comprising a modified GLA domain that enhances membrane binding affinity of said polypeptide relative to a corresponding native vitamin K-dependent polypeptide, said modified GLA domain comprising at least one amino acid substitution at residue 11, 12, 29, or 34, and wherein said polypeptide increases clot formation. Claim 4 depends from Claim 1 with the addition that the polypeptide comprises an additional substitution at position 33. Claims 1 and 4 differ from the present claims herein in that they are drawn to the genus of vitamin K-dependent proteins and not the specific members such as Factor VII claimed herein. Claims 1 and 4 also differ in that they include the additional limitation that the polypeptide must increase clot formation. Claims 1 and 4 differ from the dependent claims herein in that it fails to recite the specific amino acids to be substituted at the specific positions claimed. However, U.S. Patent No. 6,017,822

teaches that factor VII is a vitamin K dependent polypeptide that may be modified to enhance membrane binding affinity (Col. 7-8 and Ex. 1 and 2) and that modifying factor VII would provide the benefit of lowering the dosage necessary in treatment (Col. 2, lines 35-40). U.S. Patent No. 6,017,822 also teaches that substituting glutamine, glutamate or aspartate at position 10; phenylalanine at position 29; and/or aspartate at position 33 (all positions relative to the factor VII sequence) would result in the desired effect (enhancement of membrane binding; see Col. 7, lines 30-50). Moreover, specifically substituting glutamine at position 11 and glutamate at position 33 is disclosed as resulting in a polypeptide with much higher affinity for membranes and having much higher activity in autoactivation, in factor Xa generation and in several blood clotting assays (Col. 7, lines 55-57). Therefore, it would have been obvious to select factor VII from the vitamin K dependent proteins claimed in U.S. Patent No. 6.017,882 and make the specific amino acid changes claimed in the present application. One having ordinary skill in the art would have been motivated to choose factor VII and the specific modifications presently claimed since U.S. Patent No. 6, 017, 882 teaches that these modifications result in enhanced membrane binding and that enhanced membrane binding in factor VII would be desirable since it would allow for administration of lower doses of factor VII in therapy.

The examiner acknowledges that a restriction requirement was made in the parent application, however, the restriction appears to have been made subject to non-allowance of a generic claim (see Paper No. 3 in Appl. No. 08/955,636, see specifically

p. 4, lines 12-14 of the Office Action) and the generic claim (to vitamin K-dependent polypeptides) was allowed. Thus, the double patenting rejection above applies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (703) 305-3722. The examiner can normally be reached on Mon. & Thurs., 8am-5:30pm and Tues. & Wed. 9-2:30. ***The examiner will be on extended leave from Sept. 14- Nov. 1. Any inquiries during this time may be directed to the examiner's supervisor as per instructions below.***

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703 308-0196.

Holly Schnizer
September 3, 2002

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER